

EPA REGISTRATION NUMBER 82633-35

PROCESSING REQUEST

Reg. # 82633-35

Decision # 536406

Description: New Registration

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated: 10/17/2018

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated: 12/07/2017

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: BeWanda Alexander

Division: RD

Phone: (703)347-0313

Date: October 18, 2018



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

82633-35

Date of Issuance:

10/17/18

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Sharda Flumetsulam Technical

Name and Address of Registrant (include ZIP Code):

Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640, 7217 Lancaster Pike Suite A
Hockessin, DE 19707

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 82633-35."
3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Signature of Approving Official:

Erik Kraft, Product Manager 24
Fungicide Herbicide Branch, Registration Division (7505P)

Date:

10/17/18

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/07/2017

If you have any questions, please contact BeWanda Alexander by phone at (703) 347-0313, or via email at Alexander.bewanda@epa.gov.

Enclosure

Sharda Flumetsulam Technical

For Manufacturing Use Only

Active Ingredient:	% By Wt.
Flumetsulam: N-(2,6-difluorophenyl)-5-methyl-1,2,4-triazolo-[1,5a]-pyrimidine-2-sulfonamide	98.90%
Other Ingredients:	1.10%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBERS	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-hour medical emergency assistance (human or animal) call 1-800-222-1222 . For chemical emergency assistance (spill, leak, fire, or accident) call ChemTrec at 1-800-424-9300 .	

[See Panel for First Aid, Precautionary Statements, Directions For Use, and Storage and Disposal.]

EPA Reg. No.: 82633-GL

EPA Est. No.: _____

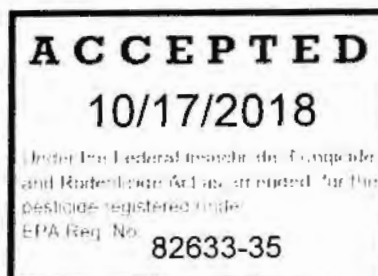
Net Contents: _____ Lbs./Kgs.

Manufactured For:

Sharda Cropchem Ltd.

2nd Floor, Prime Bus. PK., Dashrathlal Joshi Road

Vile Parle (West), Mumbai - 400056



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing (dust, vapor or spray mist). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or regional office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Manufacturing Use Only

- For formulation into an end-use herbicide only for use on corn or soybeans.
- All other uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
- Uses for experimental purposes that are in compliance with EPA requirements.

Formulators using this product are responsible for obtaining EPA registration of their formulated end-use products. Refer to Sharda Cropchem Ltd. for instructions for formulations and other information.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool dry place. Store in original container only. In case of leak or spill, contain material and dispose of as waste.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

[Drums] Refillable container. Refill this container with this pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into manufacturing equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into manufacturing equipment or rinsate collection system. Repeat this rinsing procedure two more times.

[Lined Fiber Drum] Nonrefillable container. Do not reuse or refill this container. Completely empty inner liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Dispose of inner liner in a secure landfill or by incineration if allowed by state and local authorities. Offer for recycling if available. Offer for reconditioning, if appropriate. If drum cannot be recycled or reconditioned, puncture and dispose of in a secure landfill or by other procedures allowed by state and local authorities.

[Supersack Bags] Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by other procedures allowed by state and local authorities.

For minor spills, follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

WARRANTY AND DISCLAIMER STATEMENT

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sharda Cropchem Ltd. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHARDA CROP CHEM LTD. MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Sharda Cropchem Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHARDA CROP CHEM LTD. DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT SHARDA CROP CHEM LTD.'S ELECTION, THE REPLACEMENT OF PRODUCT.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)



- Contains Confidential Business Information -

DP BARCODE No.: 444760; **FILE SYMBOL No.:** 82633-GL; **PRODUCT NAME:** Sharda Flumetsulam Technical; **DECISION No.:** 536406; **PC Code(s):** 129016; **ACTION CODE:** R333 **FOOD Use:** YES

DATE OUT: October 16, 2018

SUBJECT: Product Chemistry Review for "Sharda Flumetsulam Technical."
-Substantially Similar ("Me-Too") Registration Claim

FROM: Maria I. Rodriguez, Chemist
Product Chemistry Reviewer
CITAB/RD (7505P)

Maria I. Rodriguez

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
CITAB/RD (7505P)

S. Mathur
10.17.18

TO: Erik Kraft, RM#24
FHB/RD (7505P)

INTRODUCTION:

The CITAB (Chemistry) has been asked to determine the acceptability of supporting Product Chemistry data submitted with this application.

Registrant: Wagner Regulatory Associates, Inc., On Behalf of Sharda Cropchem Ltd.

Application Date: December 7, 2017

Proposed Product: Intended for use in formulating herbicides only for the use(s) indicated on the label

Supporting Data: Basic CSF; MRID Nos 504521-01 to -06; Data Matrix (12-07-2017)

Claim: Substantially Similar to EPA Reg No 62719-223 ("Flumetsulam 98% Milled Concentrate")

45/90-Day Completeness Screen: NO Screen Due to Time Constraints

SUMMARY OF FINDINGS:

1. This product is produced by an integrated batch process.
2. All impurities have been assayed and identified by the registrant. None of the impurities were declared of toxicological concern at the maximum level indicated.
3. The Nominal Concentration of the active ingredient on the proposed Basic CSF is 98.90%. The Nominal Concentration of the proposed Basic formulation falls within the upper and lower certified limits of 100.00 and 95.93%, respectively. All the data is supported by 5-batch analysis.
4. The active ingredient's certified limits as proposed on the Basic CSF satisfy the requirement.
5. The proposed Basic CSF for the proposed product satisfy the data requirements as specified in 40 CFR §158.310 for product identity and composition (830.1550).
6. a. Data submitted for Group A Data under the 830 Series satisfies the data requirements as specified in 40 CFR § 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to identity and composition, description of materials used to produce the product, description of the production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.
7. Data submitted for Group B Data under the 830 Series satisfies the data requirements as specified in 40 CFR §158.310 with respect to physical and chemical properties.
8. The proposed product is not substantially similar to the cited product, EPA Reg No 62719-223 ("*Flumetsulam 98% Milled Concentrate*"), as the impurity profiles are different.

CONCLUSIONS:

The CITAB (Chemistry) has reviewed this submission and concludes the following:

1. The proposed Basic CSF dated 12-07-2017 for the product is acceptable. It is attached to this review and stamped/signed "acceptable" by the CITAB – Chemistry.
2. The data submitted for Group A Data under the 830 Series are acceptable.
3. The data submitted for Group B Data under the 830 Series are acceptable.
4. The proposed product is not substantially similar to the cited product as the impurity profiles are different.

830.1800: Enforcement Analytical Method (MRID No 504521-02)

General information provided by the registrant:

Five (5) batches were analyzed by HPLC - DAD in duplicate.

The composition of the five batches was analyzed for active ingredient and impurities.

Information on the pertinent equipment and operating conditions was provided for the analysis of the active ingredient and the impurities. All the methods were validated. All the studies complied with GLP.

Chromatograms and pertinent calculations for each batch were provided in the study.

Additional information is provided under the "Preliminary Analysis" (8360.1700) section of this review.

The proposed formulation is supported by the data.

830 Series - Subgroup A (Product Identity, Composition, and Analysis):

Table 1. Manufacturing and Impurity Data for Sharda Flumetsulam Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity & Composition	504521-01 CSF	A	-The proposed NC (98.90%) of the AI falls within the upper and lower certified limits of the proposed basic formulation -Supported by 5-batch analyses -Impurities listed on CSF -No impurities of toxicological concern
830.1600	Description of Materials Used to Produce the Product	504521-01	A	-Starting materials listed and described -Chromatograms, Certificate of Analysis, and/or MSDSs provided
830.1620	Description of Production Process	504521-01	A	-Batch process described in detail -Chemical schematics with information on materials and equipment provided -Main reaction mechanisms and side reaction mechanisms provided to show process and quality control
830.1670	Discussion of Formation of Impurities	504521-01	A	-Possible impurities discussed -Data supported by 5-batch analyses
830.1700	Preliminary Analysis	504521-02	A	-Purity of AI tested in duplicate -No Impurities of toxicological concern -Impurities listed on CSF -Validated for AI and impurities -Data supported by 5-batch analysis
830.1750	Certified Limits	504521-01	A	-Purity of AI tested in duplicate -No Impurities of toxicological concern -Impurities listed on CSF -Validated for AI and impurities -Certified limits differ from basic formulation -Data supported by 5-batch analyses
830.1800	Enforcement Analytical Method	504521-02	A	-HPLC - DAD -All methods validated

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data Gap;
 I = In progress or In Need of Upgrade; U = Up-grade (additional information required)

Manufacturing process information may be entitled to confidential treatment

830 Series - Subgroup B (Physical and Chemical Properties):

Guideline Number	Study Title	Value or Qualitative Description	CITAB's Assessment	MRID Number
830.6302	Color	Beige/Brown	A	504521-03 504521-04
830.6303	Physical State	Solid	A	504521-03 504521-04
830.6304	Odor	Mild odor	A	504521-03 504521-04
830.6313	Stability to Normal & Elevated Temperatures, Metal, and Metal Ions	-Stable in Al acetate, Al, Pb acetate, Pb -Stable @ 54 °C for 2 weeks	A	504521-04
830.6314	Oxidation/reduction	Stable in NH ₄ H ₂ PO ₄ , Fe, Zn, (NH ₄) ₂ Cr ₂ O ₇ , Ca(NO ₃) ₂ , H ₂ O	A	504521-03
830.6315	Flammability	Not flammable	A	504521-03
830.6316	Explosibility	Stable to shock, friction, heat/confinement	A	504521-05
830.6317	Storage stability	Stable @ 54 °C for 2 weeks	A	504521-04
830.6319	Miscibility	NA – No data submitted	NA	504521-06
830.6320	Corrosion characteristics (MRID No 504521-06 refers to 504521-04)	After 2 weeks @ 54 °C -Stable in aluminum, copper, iron, zinc -Corrosive in polyethylene	A	504521-04 504521-06
830.6321	Dielectric Breakdown Voltage	NA – No data submitted	NA	504521-06
830.7000	pH	4.7 @ 21.5 °C	A	504521-03
830.7050	UV/Visible Absorption (λ = nm; ε = M ⁻¹ x cm ⁻¹)	-Acid media: λ = 212.60; ε = 34761.48 λ = 268.80; ε = 6264.49 -Neutral media: λ = 212.60; ε = 35488.04 λ = 269.60; ε = 6329.08 -Basic media: λ = 278.20; ε = 6469.95 λ = 235.80; ε = 9407.88	A	504521-03
830.7100	Viscosity	NA – No data submitted	NA	504521-06
830.7200 830.7220	Melting Point Boiling Point	MP = 252.1 – 258.2 °C (Measured) MP = 249.9 – 256.0 °C (Corrected) (MRID No 504521-06 indicates BP is NA)	A	504521-05 504521-06
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	1.6616 g/mL	A	504521-03
830.7370	Dissociation Constant in Water	pKa = 5.11 @ 20 °C	A	504521-03
830.7520	Particle Size & Related	NA – Product a water-soluble solid	NA	504521-06
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Log P _{OW} = 0.21 (PL – USDA Database)	A	504521-06
830.7840 830.7860	Solubility – Water Solubility - Organic Solvents	Water: 49 mg/L @ pH 2.5 (PL = Tomlin, C)	A	504521-06
830.7950	Vapor Pressure	0.0000000000278 mmHg (PL = Tomlin, C)	A	504521-06

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable; I = In Progress; U = Upgradeable

DP BARCODE No.: 444760; FILE SYMBOL No.: 82633-GL; PRODUCT NAME: Sharda Flumetsulam
Technical; DECISION No.: 536406; PC Code(s): 129016; ACTION CODE: R333 FOOD Use: YES

CONFIDENTIAL APPENDIX:

Information as provided by the Registrant.

830.1550. Product Identity & Composition:

Common Name: Flumetsulam

Chemical Name: N-(2,6-Difluorophenyl)-5-methyl(1,2,4)triazolo(1,5-a)pyrimidine-2-sulfonamide

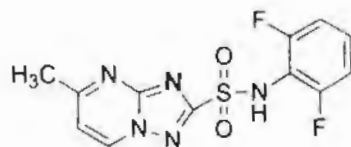
CAS No.: 98967-40-9

PC Code No.: 129016

Empirical Formula: C₁₂H₉N₅O₂S

Molecular Weight: 352.29 g/mol

Structural Formula:



CONFIDENTIAL APPENDIX

Group A-GLN Nos 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, & 830.1800: Composition (CSF), Impurities, Preliminary Analysis, and Analytical Methods

830.1550: Product Identity & Composition (Basic CSF and MRID No 504521-01):

Details about the name, manufacturing, and composition were provided by the registrant. [REDACTED] were identified as being present in the Basic formulation. The proposed Nominal Concentration of the active ingredient on the Basic CSF is 98.90%. The Nominal Concentration of the proposed Basic formulation falls within the upper and lower certified limits of 100.00 and 95.93%, respectively. All the data is supported by 5-batch analysis.

830.1600: Description of Materials Used to Produce the Product (MRID No 504521-01):

The Registrant provided the following information:

Sharda Flumetsulam Technical will be produced at:

[REDACTED]

The starting materials are listed as follows:

[REDACTED]

Pertinent information and/or MSDSs as appropriate for the starting materials.

The proposed Basic formulation is supported by the data.

830.1620: Description of Production Process (MRID No 504521-01):

The following reaction schemes were provided by the Registrant to depict how the product is synthesized in a batch process.

[REDACTED]

Manufacturing process information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

All the data is supported by 5-batch analysis.

830.1670: Discussion of the Formation of Impurities (MRID No 504521-01):

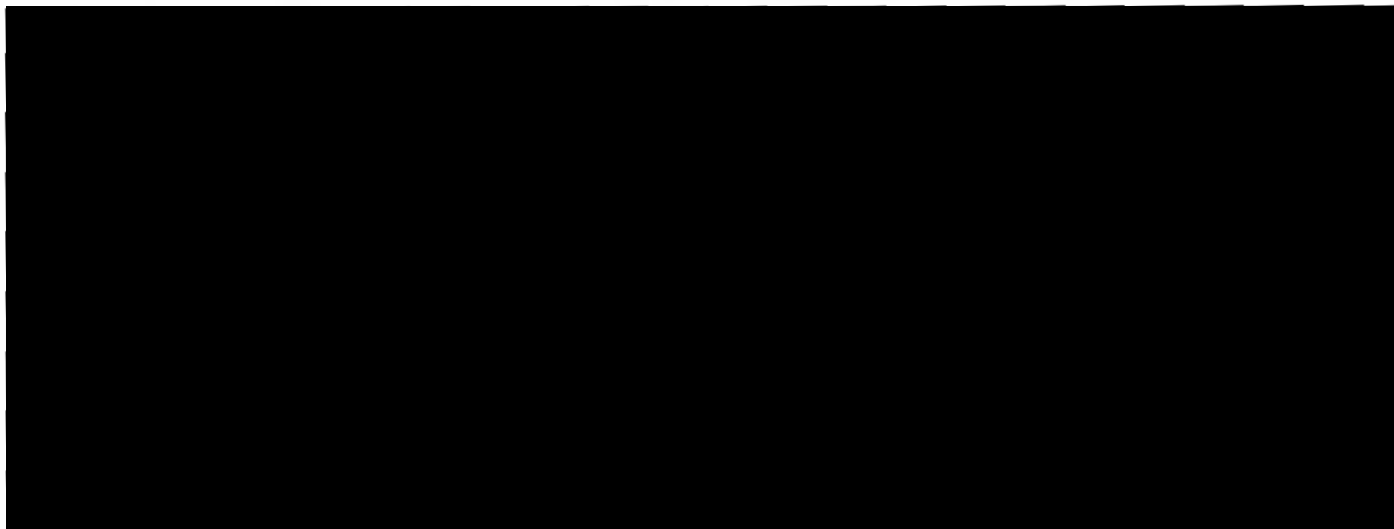
The following information was provided by the Registrant on the formation of impurities:

-There were no significant impurities that were detected and identified at an amount greater than 0.1% during the production process

All the data is supported by 5-batch analysis.

830.1700: Preliminary Analysis (MRID No 504521-02):

Five (5) batches of the product were analyzed by HPLC – DAD in duplicate for active ingredient and impurities and the results are provided below. Information on the pertinent equipment and operating conditions was provided. All the methods were validated. All the studies complied with GLP. Additional information is provided under the "Enforcement Analytical Method" (830.1800) section of this review. Chromatograms and pertinent calculations for each batch were provided in the study. Additional information is provided under the "Product Identity & Composition" (830.1550) section of this review.



Quality control process information may be entitled to confidential treatment

CC: OPPIN – OPP Chemistry Documents (OPPIN CHEM DOCS)

Attachment: Basic CSF (1 page)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

28/AUG/2018

MEMORANDUM

Subject: Name of Pesticide Product: Sharda Flumetsulam Technical
EPA Reg. No. /File Symbol: 82633-GL
DP Barcode: D444762
Decision No: 536406
Action Code: R333
PC Code: 129016 (flumetsulam)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

Through: P. V. Shah, Ph.D., Chief *P.V. Shah*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P) *8/30/2018*

To: Driss Benmhend, Risk Management Team 24
Fungicide and Herbicide Branch
Registration Division (7505P)

Applicant: Sharda Cropchem Ltd.
c/o Wagner Regulatory Consulting Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Flumetsulam	98.90
Other ingredients:	1.10
Total:	100.00

ACTION REQUESTED: Similarity determination for 82633-GL, proposed product, and 62719-223, cited product.

BACKGROUND: Sharda Cropchem Ltd. has applied for registration of Sharda Flumetsulam Technical, EPA File Symbol 82633-GL, claiming to be substantially similar to Flumetsulam Technical Herbicide, EPA Reg. No. 62719-223. Both products are technical grade for manufacturing use only. The submission includes a basic CSF dated December 7, 2017, label, data matrix and company letter.

The registrant is using the cite all method of data support to satisfy the acute toxicity data requirements. A search of the electronic regulatory jacket for 62719-223 shows that acute toxicity studies were submitted to support its registration. The studies were reviewed in two Health Effects Division memos (Doyle; TXR 0007935; 17/MAY/1990 and Williams; TXR 009586; 10/JULY/1992). The studies were conducted on technical flumetsulam.

RECOMMENDATIONS:

1. We compared the basic CSFs and labels for the proposed product, 82633-GL, and the cited product, 62719-223, and determined that the two products are substantially similar.
2. The acute toxicity profile for the proposed product, Sharda Flumetsulam Technical, EPA File Symbol 82633-GL, based on 62719-223, is as follows:

acute oral toxicity	IV	cited	EPA Reg. No. 62719-223
acute dermal toxicity	III	cited	EPA Reg. No. 62719-223
acute inhalation toxicity	III	cited	EPA Reg. No. 62719-223
primary eye irritation	IV	cited	EPA Reg. No. 62719-223
primary skin irritation	IV	cited	EPA Reg. No. 62719-223
dermal sensitization	negative	cited	EPA Reg. No. 62719-223

3. The proposed basic CSF submitted for 82633-GL must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product:

PRODUCT ID #: 82633-GL

PRODUCT NAME: Flumetsulam Technical

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing (dust, vapor or spray mist). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA PACKAGE BEAN SHEET

Date: 15-Dec-2017

Page 1 of 1

Decision #: 536406

DP #: (444762)

PRIA

Parent DP #:

Submission #: 1012848

E-Sub #: 24894

*** Registration Information ***

Registration: 82633-GL - Sharda Flumetsulam Technical

Company: 82633 - SHARDA CROPChem LIMITED

Risk Manager: RM 24 - Erik Kraft - (703) 308-9358 Room# PY1 S-7333

Risk Manager Reviewer: Driss Benmhend DBENMHEN

Sent Date:

PRIA Due Date: 29-Oct-2018

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF

Ingredients: 129016, Flumetsulam(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 15-Dec-2017

Due Back:

DP Ingredient: 129016, Flumetsulam

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / CITAB

Last Possible Science Due Date: 30-Aug-2018

Team Name: TOX

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Hello:

This is a submission by Sharda Cropchem to support the application to register a new technical product. The registrant claims that this product is similar to 62719-223. All the supporting data are in Documentum. Please perform the technical screen and send me your report by March 15, 2018. If everything is OK, proceed with the full review. The following data are attached:

¿Cover letter

¿Data matrix

¿CSF and label

Thanks

Driss

308-9525

DATA PACKAGE BEAN SHEET

Date: 15-Dec-2017

Page 1 of 1

Decision #: 536406

DP #: (444762)

PRIA

Parent DP #:

Submission #: 1012848

E-Sub #: 24894

*** Registration Information ***

Registration: 82633-GL - Sharda Flumetsulam Technical

Company: 82633 - SHARDA CROPCHEM LIMITED

Risk Manager: RM 24 - Erik Kraft - (703) 308-9358 Room# PY1 S-7333

Risk Manager Reviewer: Driss Benmhend DBENMHEN

Sent Date:

PRIA Due Date: 29-Oct-2018

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF

Ingredients: 129016, Flumetsulam(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 15-Dec-2017

Due Back:

DP Ingredient: 129016, Flumetsulam

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / CITAB

Last Possible Science Due Date: 30-Aug-2018

Team Name: TOX

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Hello:

This is a submission by Sharda Cropchem to support the application to register a new technical product. The registrant claims that this product is similar to 62719-223. All the supporting data are in Documentum. Please perform the technical screen and send me your report by March 15, 2018. If everything is OK, proceed with the full review. The following data are attached:

✓ Cover letter

✓ Data matrix

✓ CSF and label

Thanks

Driss

308-9525

DATA PACKAGE BEAN SHEET

Date: 15-Dec-2017

Page 1 of 2

Decision #: 536406

DP #: (444760)

PRIA

Parent DP #:

Submission #: 1012848

E-Sub #: 24894

*** Registration Information ***

Registration: 82633-GL - Sharda Flumetsulam Technical

Company: 82633 - SHARDA CROP CHEM LIMITED

Risk Manager: RM 24 - Erik Kraft - (703) 308-9358 Room# PY1 S-7333

Risk Manager Reviewer: Driss Benmhend DBENMHEN

Sent Date:

PRIA Due Date: 29-Oct-2018

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R333) NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF

Ingredients: 129016, Flumetsulam(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 15-Dec-2017

Due Back:

DP Ingredient: 129016, Flumetsulam

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / CITAB

Last Possible Science Due Date: 30-Aug-2018

Team Name: CHEM

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Hello:

This is a submission by Sharda Cropchem to support the application to register a new technical product. All the supporting data are in Documentum. Please perform the technical screen and send me your report by March 15, 2018. If everything is OK, proceed with the full review. The following data are attached:

1. Cover letter
2. Data matrix
3. CSF and label
4. Thanks
Driss
108-9525

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50452101		Armstrong, A. (2017) Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits. Unpublished study prepared by Sharda Cropchem Limited. 68p.	830.1550/Product Identity and composition	Not Reviewed (08-Dec-2017)
50452101		Armstrong, A. (2017) Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits. Unpublished study prepared by Sharda Cropchem Limited. 68p.	830.1600/Description of materials used to produce the product	Not Reviewed (08-Dec-2017)
50452101		Armstrong, A. (2017) Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits. Unpublished study prepared by Sharda Cropchem Limited. 68p.	830.1620/Description of production process	Not Reviewed (08-Dec-2017)
50452101		Armstrong, A. (2017) Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits. Unpublished study prepared by Sharda Cropchem Limited. 68p.	830.1670/Discussion of formation of impurities	Not Reviewed (08-Dec-2017)
50452101		Armstrong, A. (2017) Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits. Unpublished study prepared by Sharda Cropchem Limited. 68p.	830.1750/Certified limits	Not Reviewed (08-Dec-2017)
50452102		Hernandez, S. (2017) 5BA of Flumetsulam Technical: Final Report. Project Number: E17110. Unpublished study prepared by Cambium, S.L. 83p.	830.1700/Preliminary analysis	Not Reviewed (08-Dec-2017)
50452102		Hernandez, S. (2017) 5BA of Flumetsulam Technical: Final Report. Project Number: E17110. Unpublished study prepared by Cambium, S.L. 83p.	830.1800/Enforcement analytical method	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.6302/Color	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.6303/Physical state	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.6304/Odor	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.6314/Oxidizing or reducing action	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.6315/Flammability	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.7000/pH	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.7300/Density/relative density	Not Reviewed (08-Dec-2017)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.7370/Dissociation constants in water	Not Reviewed (08-Dec-2017)
50452103		Hernandez, S. (2017) Flumetsulam Technical: Physical-Chemical Properties: Final Report. Project Number: E17116. Unpublished study prepared by Cambium, S.L. 48p.	830.7520/Particle size, fiber length, and diameter distribution	Not Reviewed (08-Dec-2017)
50452104		Hernandez, S. (2017) Flumetsulam Technical: Accelerated Storage at 54 Degrees Celsius / 14 Days: Final Report. Project Number: E17117. Unpublished study prepared by Cambium, S.L. 51p.	830.6302/Color	Not Reviewed (08-Dec-2017)
50452104		Hernandez, S. (2017) Flumetsulam Technical: Accelerated Storage at 54 Degrees Celsius / 14 Days: Final Report. Project Number: E17117. Unpublished study prepared by Cambium, S.L. 51p.	830.6303/Physical state	Not Reviewed (08-Dec-2017)
50452104		Hernandez, S. (2017) Flumetsulam Technical: Accelerated Storage at 54 Degrees Celsius / 14 Days: Final Report. Project Number: E17117. Unpublished study prepared by Cambium, S.L. 51p.	830.6304/Odor	Not Reviewed (08-Dec-2017)
50452104		Hernandez, S. (2017) Flumetsulam Technical: Accelerated Storage at 54 Degrees Celsius / 14 Days: Final Report. Project Number: E17117. Unpublished study prepared by Cambium, S.L. 51p.	830.6317/Storage stability	Not Reviewed (08-Dec-2017)
50452105		Gonzalez, M. (2017) Determination of Explosive Properties and Melting Point of Flumetsulam Technical. Project Number: 17/4150/12. Unpublished study prepared by Laboratorios Munuera, S.L.U. 25p.	830.7200/Melting point/melting range	Not Reviewed (08-Dec-2017)
50452105		Gonzalez, M. (2017) Determination of Explosive Properties and Melting Point of Flumetsulam Technical. Project Number: 17/4150/12. Unpublished study prepared by Laboratorios Munuera, S.L.U. 25p.		Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.6319/Miscibility	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.6320/Corrosion characteristics	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.6321/Dielectric breakdown voltage	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7100/Viscosity	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7220/Boiling point/boiling range	Not Reviewed (08-Dec-2017)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7520/Particle size, fiber length, and diameter distribution	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7560/Partition coefficient (n-octanol/water), generator column method	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7570/Partition coefficient (n-octanol/water), estimation by liquid chromatography	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7840/Water solubility: Column elution method, shake flask method	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7860/Water solubility, generator column method	Not Reviewed (08-Dec-2017)
50452106		Armstrong, A. (2017) Flumetsulam Technical: Product Chemistry - Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data. Unpublished study prepared by Sharda Cropchem Limited. 4p.	830.7950/Vapor pressure	Not Reviewed (08-Dec-2017)

Decision Seq: 536406 Action Code: R333,NEW PRODUCT;MUP OR END USE PRODUCT WITH UA ... ?

Decision Status

Tentative Start Date: 28-Dec-2017 Tentative Ind: Yes Start/Stop Clock: FQPA Clock:

Tracking

Tentative Due Date: 29-Oct-2018 75-Day Due Date: Days Elapsed:


Create Resubmission

OPP Target Due Date: 21-Day Due Date: 28-Dec-2017 FFS Original Decision: ...

FFS Letters

Negotiated Due Date: 90-Day Due Date: 28-Mar-2018

Action Code History




Registrant:  Predecisional Due Date: 15-Oct-2018 Add to Bundle? ☐

Secondary Decision

Response Due Date: ☐ Bundle ID:

Decision Bundle

Current Status: PENDING (11-Dec-2017)

 75 Day Letters  45/90 Day Screen Primary Decisions Decision Milestone FFS Negotiated Due Dates  OPP Target Due Date Decision Comments  Decision Ownership Receipts  Data Package ☐ Reduced Risk Meetings & Milestones  FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
----------	--------------	----------------	-------------------	----------

 S:1012848	Benmhend, Driss	... 82633-GL	29-Oct-2018	PENDING
---	-----------------	--------------	-------------	---------

New technical Active Ingredient

Viewing Record 1 of 1

Fungicide-Herbicide Branch Assignment Sheet

Date to PM 12-14-2017

(date & initials)

ka

Shaja - PM 20

Erik - PM 24

Note to PM: Please indicate the action code

Notification _____

Fast Track Amendment _____

PRIA ✓

Other _____

Risk Managers

Aswathy

BeWanda

Driss

Eleanor

Gene

Lisa

Nate

Write in

Comments to BeWanda/Eleanor _____

Comments to Risk Manager _____

Date to BeWanda/Eleanor _____

(date & initials)

21-Day Screen Completed by
Contractor

21-Day Expires on 12-28-17

Jacket # 82633-GL
MRID# 504521

Content Screen: Recommend to ☒ **Pass** ☐ **Fail**

11-3 Review: ☒ **Pass** ☐ **Fail** ☐ **NA**

Overall Status: Recommend to ☒ **Pass** ☐ **Fail**

Transfer This Jacket to:

DAN KENNY

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-7-17

Experts In-Processing Signature: B.B. Date 12-12-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>82633-GL</u>		EPA Receipt Date: <u>12-7-17</u>								
Items for Review				Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type			X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>NO inerts to review</u>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X						
	Certificate and data matrix consistent			X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no									
	If applicable, is there a letter of Authorization for exclusive use only.									
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X				
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X						
5	a) Selective Method (Fee category experts use)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no									
X										
	b) Cite-All (Fee category experts use)									
	c) Applicant owns all data (Fee category experts use)									
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X						
7	Is the data package consistent with PR Notice 86-5			X						
8	Notice of Filing included with petitions					X				

9	If applicable for conventional applications, <u>reduced risk rationale</u>			
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

DOCUMENTATION: PASS

Required forms are complete

INERTS: PASS

NO INERTS TO REVIEW, TECHNICAL + WATER + IMPURITIES ONLY

PRN 11-3: PASS

MRID: 504521

OVERALL STATUS: PASS

MR 12/13/17

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 11, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-536406
EPA File Symbol or Registration Number: 82633-GL
Product Name: Sharda Flumetsulam Technical
EPA Receipt Date: 07-Dec-2017
EPA Company Number: 82633
Company Name: SHARDA CROP CHEM LIMITED

MS. ANNA ARMSTRONG
WAGNER REGULATORY ASSOCIATES, INC.
SHARDA CROP CHEM LIMITED
PO Box 640, 7217 LANCASTER PIKE, SUITE A
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in dark ink, appearing to be "J. Mc" or similar, written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division



This package includes the following

- Amendment

☐ volpay % Reduction: _____

for Division

- BPPD

RD

Risk Mgr.

24

S-

1012848

82633-GL

12/7/2017

Action Code:

R333

R333

Parent/Child Decisions:

5

Reviewer:

Date: 12/1/17

Remarks:

S: 1012848

Milestone Email: anna@wagnerreg.com

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company: 82633 SHARDA CROP CHEM LIMITED

Risk Manager: Registration Division, Risk Management Team 24

Product #: 82633-GL

Product Name: Sharda Flumetsulam Technical

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

V

☐ Me Too
Section 3:

Me Too Product
Name

Application Date: 07-Dec-2017



OPP Rec'd Date: 07-Dec-2017



Front End Date: 08-Dec-2017



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:



New Ingredient: ☐

Receipt Description:

Portal submission pkg# 24894 PRIA R333 New registration

Receipt Content

Study

CSF

View/Edit

From: notification@pay.gov
To: Anna Armstrong
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Thursday, December 7, 2017 11:05:14 AM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 266EJ0NV
Agency Tracking ID: 75378561663
Transaction Type: Sale
Transaction Date: 12/07/2017 11:05:09 AM EST

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$19,838.00
Card Type: AmericanExpress
Card Number: *****2008

Registration Number:
Company Name: Sharda CropChem
Company Number: 82633
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Submitted Electronically

December 7, 2017

Document Processing Desk (REGFEE)
Attn: Erik Kraft PM 24
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

WRA

Wagner Regulatory Associates, Inc.
P.O. Box 640
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707

Subject: Sharda Cropchem Ltd., Company No. 82633
Application to Register a New Technical Grade Active Ingredient - Sharda Flumetsulam
Technical
PRIA R333 - \$19,838

Dear Mr. Kraft:

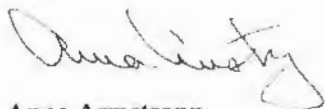
Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd. (EPA Co. 82633), is requesting registration of the above referenced proposed technical grade active ingredient product.

In support of this request, the following documents and studies are being submitted electronically via the EPA CDX PSP portal:

- Letter from Sharda Cropchem Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Confidential Statement of Formula (8570-4)
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35) - Internal and Public versions
- Data Transmittal Document
- Data Reports as Outlined in the Transmittal Document
- Draft Label
- Certification with Respect to Label Integrity
- Receipt Confirming Payment of PRIA fee for category R333 - \$19,838

Thank you in advance for your efforts in reviewing this submission. Please do not hesitate to contact me by email at anna@wagnerreg.com or by phone at 302-510-0039 should you have any questions.

Respectfully submitted,



Anna Armstrong
Agent for Sharda Cropchem Ltd.

Enclosures

DATA TRANSMITTAL DOCUMENT**1. Name and Address of Submitter**

Sharda Cropchem Ltd.
 c/o Wagner Regulatory Associates, Inc.
 P.O. Box 640, 7217 Lancaster Pike, Suite A
 Hockessin, DE 19707
 EPA Company No. 82633

2. Regulatory Action In Support Of Which This Package Is Submitted

Application for Registration
Sharda Flumetsulam Technical

3. Transmittal Date

December 7, 2017

4. List of Submitted Studies

50452101	Flumetsulam Technical Product Identity and Composition, Description of Materials, Manufacturing Process, Discussion of Formation and Toxicity of Impurities and Certified Limits, OPPTS: 830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750
50452102	SBA of Flumetsulam Technical, Study No. E17116, OPPTS: 830.1700, 830.1800
50452103	Flumetsulam Technical Physical-Chemical Properties, Study No. E17116, OPPTS: 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 30.7000, 830.7050, 830.7300, 830.7370
50452104	Flumetsulam Technical Accelerated Storage at 54°C / 14 Days, Study No. E17117, OPPTS: 830.6317
50452105	Determination of Explosive Properties and Melting Point of Flumetsulam Technical, Study No. 17-4150-12, OPPTS: 830.7200
50452106	Flumetsulam Technical Product Chemistry – Group B: Request for Waiver and Citation of Data for Certain Physical / Chemical Properties Data, OPPTS: 6319; 6320; 6321; 7100; 7220; 7520; 7550; 7560; 7570; 7840; 7860; 7950

Company Name: Sharda Cropchem Ltd.

Company Official: Anna Armstrong
Authorized Agent


Signature

Company Contact: Anna Armstrong
Authorized Agent

(302) 510-0039 / anna@wagnerreg.com
Phone / Email



United States
Environmental Protection Agency
 Washington, DC 20460

**Registration**

OPP Identifier Number

**Amendment****Other****Application for Pesticide - Section I**

1. Company/Product Number 82633-XX	2. EPA Product Manager Erik Kraft	3. Proposed Classification
4. Company/Product (Name) Sharda Cropchem Ltd. / Sharda Flumetsulam Technical	PM# 24	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) Sharda Cropchem Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike Suite A Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No.: 62719-223 Product Name: Flumetsulam 98% Milled Concentrate	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**PRIA R333 - New Technical Grade Active Ingredient****Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted	If "Yes" No. per	If "Yes" No. per		<input checked="" type="checkbox"/> Plastic	
	Unit Packaging wgt. container	Package wgt. container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) HDPE lined drums	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Bulk		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Anna Armstrong		Title Agent for Sharda Cropchem Ltd		Telephone No. (Include Area Code) (302) 510-0039 (anna@wagnerreg.com)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Agent for Sharda Cropchem Ltd.			
4. Typed Name Anna Armstrong		5. Date December 7, 2017			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Sharda Cropchem Ltd. P.O. Box 640, 7217 Lancaster Pike, Suite A, Hockessin, DE 19707	EPA Registration Number/File Symbol 82633-XX
Active Ingredient(s) and/or representative test compound(s) Flumetsulam	Date December 7, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Crop Uses	Product Name Sharda Flumetsulam Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 12/7/2017	Typed or Printed Name and Title Anna Armstrong, Agent
---------------	-------------------	--



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: December 7, 2017	EPA Reg. No./ File Symbol: 82633-XX	Page 1 of 2
Applicant's/Registrant's Name and Address: Sharda Cropchem Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640, 7217 Lancaster Pike, Suite A Hockessin, DE 19707	Product: Sharda Flumetsulam Technical	
Ingredient: Flumetsulam		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
830.1550, 830.1600	Product identity, composition/Description of materials Used to Produce the Product	50452101	Sharda Cropchem Ltd.	Own	
830.1620	Description of Production Process	50452101	Sharda Cropchem Ltd.	Own	
830.1670	Discussion of Formation of Impurities	50452101	Sharda Cropchem Ltd.	Own	
830.1700	Preliminary Analysis	50452102	Sharda Cropchem Ltd.	Own	
830.1750	Certification of Limits	50452101	Sharda Cropchem Ltd.	Own	
830.1800	Enforcement Analytical Method	50452102	Sharda Cropchem Ltd.	Own	
830.6302	Color	50452103	Sharda Cropchem Ltd.	Own	
830.6303	Physical State	50452103	Sharda Cropchem Ltd.	Own	
830.6304	Odor	50452103	Sharda Cropchem Ltd.	Own	
830.6313	Stability to Normal & Elevated Temperatures	50452104	Sharda Cropchem Ltd.	Own	
830.6314	Oxidation/Reduction	50452103	Sharda Cropchem Ltd.	Own	
830.6315	Flammability	50452103	Sharda Cropchem Ltd.	Own	
830.6319	Miscibility	50452106	Sharda Cropchem Ltd.	Own	
830.6320	Corrosion Characteristics	50452106	Sharda Cropchem Ltd.	Own	
830.6321	Dielectric Voltage Breakdown	50452106	Sharda Cropchem Ltd.	Own	
830.7000	pH	50452103	Sharda Cropchem Ltd.	Own	
830.7050	UV/Visible Absorption	50452103	Sharda Cropchem Ltd.	Own	
830.7100	Viscosity	50452106	Sharda Cropchem Ltd.	Own	
830.7200, 830.7220	Melting Point/Boiling Point	50452105 50452106	Sharda Cropchem Ltd.	Own	
830.7300	Relative Density	50452103	Sharda Cropchem Ltd.	Own	
830.7370	Dissociation Constant	50452103	Sharda Cropchem Ltd.	Own	
830.7520	Particle Size Distribution	50452103 50452106	Sharda Cropchem Ltd.	Own	

Signature 	Name and Title Anna Armstrong, Agent for Sharda Cropchem Ltd.	Date December 7, 2017
----------------------	---	---------------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: December 7, 2017

EPA Reg. No./ File Symbol: 82633-XX

Page 2 of 2

Applicant's/Registrant's Name and Address: Sharda Cropchem Ltd.
c/o Wagner Regulatory Associates, Inc.
P.O. Box 640, 7217 Lancaster Pike, Suite A
Hockessin, DE 19707

Product:
Sharda Flumetsulam Technical

Ingredient: Flumetsulam

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550, 830.7560, 830.7570	Octanol Water Partition Coefficient	50452106	Sharda Cropchem Ltd.	Own	
830.7840, 830.7860	Solubility	50452106	Sharda Cropchem Ltd.	Own	
830.7950	Vapor Pressure	50452106	Sharda Cropchem Ltd.	Own	
870.1100	Acute Oral Toxicity	Cite All	Dow AgroSciences LLC, Indianapolis, IN	Pay	
870.1200	Acute Dermal Toxicity	Cite All	Spray Drift Task Force, Washington, DC	Pay	
870.1300	Acute Inhalation Toxicity	Cite All	Outdoor Residential Exposure TF, Washington, DC	Pay	
870.2400	Primary Eye Irritation	Cite All	Agricultural Reentry Task Force, Washington, DC	Pay	
870.2500	Primary Dermal Irritation	Cite All	FIFRA Endangered Species Task Force, Lakewood, WA	Pay	
870.2600	Skin Sensitization	Cite All	Agricultural Handler Exposure TF, Macon, MO	Pay	
Generic Data	Generic Data	Cite All			

Signature

Name and Title

Anna Armstrong, Agent for Sharda Cropchem Ltd.

Date

December 43 2017

